

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	Civil No. <u>3:18-CV-331</u> [BKS/DEP]
)	
v.)	
)	
VULTO CREAMERY LLC,)	COMPLAINT FOR
a limited liability company,)	PERMANENT INJUNCTION
)	
and)	
)	
JOHANNES H. VULTO,)	
an individual,)	
)	
Defendants.)	
_____)	

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, to permanently enjoin and restrain Vulto Creamery LLC ("Vulto Creamery"), a limited liability company, and Johannes H. Vulto, an individual, (collectively, "Defendants"), from:

A. violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce, articles of food that are adulterated within the meaning of 21 U.S.C. §§ 342(a)(1) or (a)(4); and

B. violating 21 U.S.C. § 331(k) by doing or causing to be done any act that causes articles of food that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. §§ 342(a)(1) or (a)(4).

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345, and personal jurisdiction over all parties.

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Defendant Vulto Creamery LLC (“Vulto Creamery”) is a limited liability company that was established in New York in 2010.

5. Vulto Creamery manufactures, prepares, processes, holds, labels, packs, and distributes several varieties of ready-to-eat (“RTE”) aged soft, semi-soft, and hard cheeses made from raw cow’s milk.

6. Vulto Creamery manufactures all its cheeses at its facility located at 44 West Street, Walton, New York (“the facility”), within the jurisdiction of this Court.

7. Defendant Johannes (“Jos”) H. Vulto is the owner and manager of Vulto Creamery. He is responsible for the company’s day-to-day operations, including purchasing, selling, manufacturing, processing, holding, labeling, packing, distributing, and shipping. He also trains employees on how to make cheese and is responsible for quality assurance and quality control operations. Mr. Vulto performs his duties at the facility, within the jurisdiction of this Court.

8. Defendants’ RTE cheeses are articles of food within the meaning of 21 U.S.C. § 321(f).

9. Defendants’ RTE cheeses are sold to retail and wholesale customers nationwide, including retail locations in the northeastern and mid-Atlantic states. Defendants use one or

more ingredients shipped in interstate commerce to make their cheeses, including starter cultures and rennet received from a supplier in Wisconsin.

LISTERIA MONOCYTOGENES AND LISTERIA SPECIES

10. *Listeria monocytogenes* ("*L. mono*") is a bacterium found in soil and moist environments. It is a pathogenic organism that poses an acute, life-threatening hazard to human health because it is the causal agent for the disease listeriosis, which most commonly is contracted by eating food contaminated with *L. mono*. Listeriosis can be serious, even fatal, for high-risk individuals, such as pregnant women, infants, the elderly, and people whose immune systems are impaired by disease or medications. In pregnant women, listeriosis can cause abortion, stillbirth, and newborn fatality. The most serious forms of listeriosis also can result in meningitis and septicemia.

11. *L. mono* thrives in moist environments, such as food-manufacturing environments, where, unless proper precautions are taken, it may become established and grow. It is difficult to eliminate once it becomes established in a food-manufacturing environment and is capable of surviving and growing at refrigerated temperatures. Consequently, *L. mono* is a significant public health risk in RTE cheese, including soft RTE cheese, which usually has a relatively high moisture content and pH, both of which contribute to the survival and growth of *L. mono*. The risk is even greater when RTE cheese is made with raw milk, which is not pasteurized. Pasteurization is a heat process that reduces or kills *L. mono* and other harmful bacteria, making their potential outgrowth during the aging process less likely to occur.

12. *Listeria species* ("*Listeria spp.*") refers generally to all species within the genus *Listeria*, and includes both non-pathogenic *Listeria* and *L. mono*, to date the only species of *Listeria* known to cause foodborne illness. The presence of *Listeria spp.* on food contact

surfaces in a facility that manufactures RTE foods that support the growth of *L. mono* is indicative of insanitary conditions present during food processing.

LISTERIOSIS OUTBREAK

13. Public health officials can trace cases of listeriosis to specific foods manufactured by particular manufacturers through methods known as Pulsed-field Gel Electrophoresis (“PFGE”) and Whole Genome Sequencing (“WGS”) of *L. mono*, together with traditional epidemiologic investigations.

14. PFGE and WGS are methods used to analyze pathogens isolated from food or environmental samples that can then be compared to clinical isolates from patients. If the isolates found in the food or food production environment match the isolates from the patients, the two can be linked in a causal fashion.

15. PFGE and WGS perform the same function, but WGS is a newer and powerful DNA fingerprinting method that allows scientists to precisely characterize the complete genome of bacterial pathogens with high-resolution data that can be used to infer the evolutionary relationships within a given set of subsamples of the same bacteria. WGS allows scientists to determine, with a high degree of certainty, whether pathogens with matching genomic sequence profiles originated from the same source.

16. In January 2017, the Centers for Disease Control and Prevention (“CDC”) investigated a multistate outbreak of *L. mono* that, by the end of the investigation, sickened at least eight people, two of whom died.

17. Through epidemiological evidence gathered during the investigation, cheese produced by Defendant Vulto Creamery was identified as a potential source.

18. In February 2017, FDA and the New York State Department of Agriculture and Markets (“NYSDAM”) collected samples from two different lots of Defendants’ Ouleout cheese from retail locations in Connecticut and Massachusetts and Defendants’ facility. In addition, the state of Connecticut collected samples of cheese from one patient’s home, including cheese identified as Defendants’ Ouleout.

19. Four of the samples collected by FDA and NYSDAM, one from the Connecticut retail location and three from Defendants’ facility, tested positive for *L. mono*.

20. PFGE and WGS analysis of the *L. mono* strains isolated from these *L. mono*-positive samples, the Ouleout cheese sample from the patient’s home, and clinical outbreak isolates from each of the eight patients, showed that the strains were virtually identical, confirming that cheese manufactured and distributed by Defendants was the source of the multistate outbreak.

DEFENDANTS’ VIOLATIVE CONDUCT AND RESPONSES

21. FDA and NYSDAM jointly inspected Defendants’ facility between February 28, 2017 and March 22, 2017 (the “March Inspection”).

22. This inspection established that the RTE cheeses that Defendants manufacture, prepare, process, pack, hold, label, and distribute are: (a) adulterated within the meaning of 21 U.S.C. § 342(a)(1), in that they bear or contain a poisonous and deleterious substance, *L. mono*, which may make them injurious to health; and (b) adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or rendered injurious to health.

23. The insanitary conditions, set forth in greater detail in paragraph 24, include the presence of *Listeria spp.* in Defendants’ facility and the lack of effective monitoring and

sanitation controls required for food production under current Good Manufacturing Practice ("cGMP"), *see* 21 C.F.R. Part 110, as evidenced by the presence of *L. mono* in their cheese products.

24. During the March Inspection, FDA investigators documented many significant deviations from cGMP requirements, including, but not limited to, the following:

A. Failure to manufacture and store foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination, as required by 21 C.F.R. § 110.80(b)(2), in that finished product samples of Defendants' Ouleout raw milk cheese from two different lots were analyzed and found to be positive for *L. mono*;

B. Failure to perform microbial testing where necessary to identify sanitation failures and possible food contamination, as required by 21 C.F.R. § 110.80, in that Defendants' test records show that they conducted environmental sampling only 20 times between July 28, 2014, and February 19, 2017, and that 54 out of 198 swabs taken from various locations throughout the manufacturing facility, including food contact and non-food contact surfaces, tested positive for *Listeria spp.* Defendants did not conduct an investigation to identify the species of *Listeria* and failed to identify its source or point of entry/harborage into the facility. Additionally, Defendants did not conduct microbial testing of finished products after finding positive *Listeria spp.* on food contact surfaces, in order to confirm that the products were not contaminated with the organism found by the environmental testing program;

C. Failure to use a procedure for equipment and utensil cleaning and sanitizing that has been shown to provide adequate treatment, as required by 21 C.F.R. § 110.35(d)(5), in that Defendants repeatedly found *Listeria spp.* throughout the facility, even after re-cleaning and re-sanitizing;

D. Failure to store cleaned and sanitized portable equipment in a location and manner which protects food-contact surfaces from contamination, as required by 21 C.F.R. § 110.35(e), in that cleaned and sanitized wood boards, used to hold RTE cheeses, were stored in the facility's attic where exposed insulation and other debris were observed;

E. Failure to take necessary precautions to protect against contamination of food and food contact surfaces with microorganisms and foreign substances, as required by 21 C.F.R. § 110.10(b)(9), in that Defendants' employees did not wash their lower or upper arms prior to submerging them in whey to stir and break up in-process cheese curds, and one of these employees had multiple cuts and abrasions on his arms;

F. Failure to use equipment designed and made with materials that allow for proper cleaning, sanitizing, and maintenance, as required by 21 C.F.R. § 110.40(a). Specifically, a large majority of the wooden boards used for aging are of a design that does not allow them to be appropriately cleaned and sanitized. The boards have uneven surfaces which allow for the collection of moisture and debris and are a potential harborage area for filth and microorganisms. These wooden boards come in direct contact with Defendants' aging RTE cheese product and are used for other cheese products. The boards, moreover, are dried and stored in Defendants' attic space where they are exposed to a fan that had dirt and dust on its spinning arms and face, which could be a source of transmitting pathogenic bacteria to finished products;

G. Failure to construct the plant in such a manner as to prevent drip and condensate from contaminating food and food-contact surfaces, as required by 21 C.F.R. § 110.20(b)(4). Specifically, condensation was noted dripping from the horizontal stainless steel cheese press bar directly onto the draining table below, on which molded cheese products are

placed to drain whey. Dripping condensate in the processing environment can potentially facilitate the movement of pathogens and cause product contamination;

H. Failure to maintain physical facilities in repair and in a sanitary condition sufficient to prevent food from becoming adulterated, as required by 21 C.F.R. § 110.35(a). For example, there was a heavy buildup of rust in multiple locations, including on white painted vertical support bars that hold cheese presses in place. These bars are located directly over a draining table, and rust flakes were on the top surface of the drain table where molds of cheese are set to drain. The rust was also on a painted white metal storage shelf used to store cheese molds, other equipment, and utensils, and on a stainless steel storage shelf used to hold boxes of wrapped finished cheese products. In addition, there was heavy buildup of black mold in multiple locations in the facility, including the cement walls in the manufacturing room and washroom with which cleaning brushes and storage racks come into direct contact. The concrete floors in the manufacturing and cheese aging rooms were cracked and pitted, with moisture accumulated in the cracks and pits;

I. Failure to operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food and food-contact surface, as required by 21 C.F.R. § 110.20(b)(6). Specifically, a fan in the attic, used to dry wood boards used for cheese aging after the boards have been cleaned and sanitized, had dirt and dust debris buildup on its spinning arms and face. Additionally, a fan in the manufacturing room used to dry the floor had a very heavy buildup of unknown debris on its spinning arms and face;

J. Failure to take effective measures to exclude pests from the processing areas and protect against contamination of food by pests, as required by 21 C.F.R. § 110.35(c).

Specifically, a long piece of sticky fly tape, heavily populated with dead insects, was observed hanging directly over exposed, uncovered RTE cheeses in Defendants' cheese aging room; and

K. Failure to maintain plumbing to avoid it constituting a source of contamination to equipment and utensils, or creating an insanitary condition, as required by 21 C.F.R. § 110.37(b)(3). For example, hoses used during cleaning operations were directly connected to the potable water supply in the wash room and manufacturing room without proper backflow prevention devices.

25. At the close of the March Inspection, the FDA investigators issued a fifteen-item List of Inspectional Observations ("Form FDA-483") to, and discussed each of the observed deviations with, Defendant Johannes Vulto.

26. On March 3, 2017, at FDA's urging, Defendants agreed to recall its Ouleout cheese. On March 7, 2017, following discussion with FDA, Defendants agreed to recall all their soft and semi-soft cheese products. On March 11, 2017, following further discussion with FDA, Defendants agreed to recall all their cheese products. On March 17, 2017, Defendants agreed to destroy all cheese that was in inventory or returned, and did so on April 5, 2017.

27. In discussions with FDA following the outbreak, Defendant Johannes Vulto acknowledged that he did not understand the significance of the environmental sampling results that tested positive for *Listeria spp.*; did not understand that the positive *Listeria spp.* results were an indication that his cleaning and sanitizing treatments were inadequate in controlling the occurrences of microbiological contaminations; never thought to identify the species of *Listeria* that were isolated from food contact surfaces to determine if they were *L. mono*; after repeatedly getting positive findings of *Listeria spp.* throughout the processing environment, including food contact surfaces, never thought to conduct a root cause investigation of the *Listeria spp.*-positive

results or identify the source or point of entry/harborage into the facility; and never thought to conduct finished product testing to determine if Defendants' cheese products may have been contaminated, despite finding *Listeria spp.* on food contact surfaces.

28. On April 11, 2017, Defendants responded to the FDA-483 with a proposed Corrective Action Plan. In it, Defendants described several minor corrective actions they had taken to address some of the objectionable conditions identified during the March 2017 inspection. The majority of the response, however, consisted of promised corrections with unclear plans for implementation and no timetable. FDA determined that the Corrective Action Plan was inadequate to overcome the numerous significant violations found at the facility. For instance, Defendants did not address the source and root cause of the *L. mono* hazard, or present any detailed plans to conduct significant cleaning and sanitation of the facility to help eradicate *L. mono* from its environment. Based on Defendants' responses and lack of understanding of cGMP requirements and how to comply with them, it is extremely unlikely that Defendants will be capable of putting into place and sustaining any promised corrections and compliance.

DEFENDANTS' VIOLATIONS

29. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of food that:

A. are adulterated within the meaning of 21 U.S.C. § 342(a)(1), in that they bear or contain *L. mono*, a poisonous and deleterious substance, which may render them injurious to health; and

B. are adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or rendered injurious to health.

30. Defendants violate 21 U.S.C. § 331(k) by causing the adulteration, within the meaning of 21 U.S.C. §§ 342(a)(1) and (a)(4), of articles of food while such articles are held for sale after shipment of one or more of their components in interstate commerce.

31. Based on the foregoing, the United States is informed and believes that, unless restrained by Order of this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a) and (k) in the manner set forth above.

PRAYER FOR RELIEF

WHEREFORE, the United States respectfully requests that this Court:

I. Permanently and perpetually restrain and enjoin, under 21 U.S.C. § 332(a) and the inherent equitable authority of this Court, Defendants Vulto Creamery LLC, a limited liability company, and Johannes H. Vulto, an individual, and each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of the Court's Order, from doing or causing to be done, directly or indirectly, any of the following acts:

A. violating 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, or the causing thereof, any article of food that is adulterated within the meaning of 21 U.S.C. §§ 342(a)(1) or (a)(4); and

B. violating 21 U.S.C. § 331(k) by doing or causing to be done any act that causes any article of food to become adulterated within the meaning of 21 U.S.C. §§ 342(a)(1) or (a)(4), while such article of food is held for sale after shipment of one or more of its components in interstate commerce;

II. Order Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of the Court's Order, to cease, directly or indirectly, receiving, manufacturing, preparing, processing, holding, labeling, packing, and distributing any article of food within the meaning of 21 U.S.C. § 321(f), at or from Defendants' facility, or at any other or new location(s) at or from which Defendants, directly or indirectly, receive, manufacture, prepare, process, hold, label, pack, or distribute any article of food, unless and until Defendants bring their operations into compliance with the Act and its implementing regulations to FDA's satisfaction; and

III. Grant the United States its costs and such other and further relief as the Court deems just and proper.

Dated: March 19, 2018

Respectfully submitted,

Of Counsel:

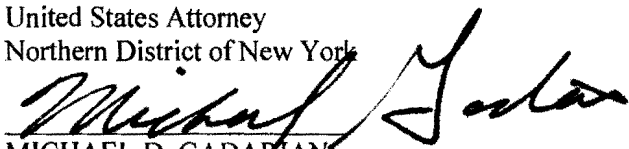
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A handwritten signature in black ink, appearing to read "Natalie N. Sanders", written over a horizontal line.

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JS 44 (Rev. 06/17)

CIVIL COVER SHEET 3:18-CV-331

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

United States of America

(b) County of Residence of First Listed Plaintiff

(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

U.S. Attorneys Office, 100 S. Clinton St. Syracuse, NY 13261

DEFENDANTSVulto Creamery LLC (a limited liability company)
Johannes H. Vulto (an individual)County of Residence of First Listed Defendant Delaware County

(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

Douglas A. Fellman, Esq.

Hogan Lovells US LLP

555 Thirteenth Street, NW; Washington, DC 20004

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☒ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | PTF | DEF | | PTF | DEF |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input checked="" type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District (specify)
- ☐ 6 Multidistrict Litigation - Transfer
- ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(a) & (k), et seq

Brief description of cause:

Introduction or delivery for introduction of adulterated food into interstate commerce and other FDCA violations

VII. REQUESTED IN COMPLAINT:
☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND:

☐ Yes ☒ No**VIII. RELATED CASE(S) IF ANY**

(See instructions):

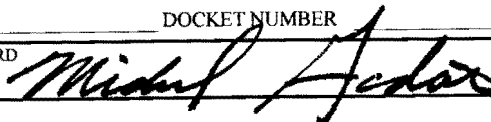
JUDGE

DOCKET NUMBER

DATE

03/19/2018

SIGNATURE OF ATTORNEY OF RECORD



FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

Waived

APPLYING IFP

JUDGE

BKS

MAG. JUDGE

DEP